

Claims

What is claimed is:

- 1 1. A process for manufacturing a tissue implant comprising obtaining tissue to be  
2 processed; scanning said tissue to produce dimensional data of said tissue; analyzing  
3 said data by a computer system enabled with a database comprising a plurality of  
4 designs; and identifying one or more designs and quantity thereof that relate to an  
5 optimized use of said tissue, whereby one or more tissue products are produced in  
6 accord with said identified one or more designs and quantity thereof.
- 1 2. The process according to claim 1, wherein said at least one tissue sample is sterilized.
- 1 3. The process according to claim 1, wherein said at least one tissue sample is allograft,  
2 autograft, or xenograft tissue, or combinations thereof.
- 1 4. The process according to claim 3, wherein said at least one tissue sample is cortical  
2 bone, cancellous bone, fascia, dermis, whole joints, tendons, ligaments, dura,  
3 pericardia, heart valves, veins, neural tissue, or submucosal tissue, cartilage, or  
4 combinations thereof.
- 1 5. A process for manufacturing tissue implants comprising:  
2 a. obtaining at least one tissue sample for processing;  
3 b. sterilizing said at least one tissue sample;  
4 c. scanning said at least one tissue sample to produce dimensional data  
5 corresponding thereto;  
6 d. inputting said data into a computer system enabled with a database comprising  
7 a plurality of designs;  
8 e. identifying one or more designs and quantity thereof that correspond to an  
9 optimal use of said at least one tissue sample; and

10 f. machining said at least on sample of tissue to produce one or more tissue  
11 products in accord with said one or more designs and quantity thereof.

1 6. The process according to claim 5, wherein said at least one tissue sample is allograft,  
2 autograft, or xenograft tissue, or combinations thereof.

1 7. The process according to claim 6, wherein said at least one tissue sample is cortical  
2 bone, cancellous bone, fascia, whole joints, tendons, ligaments, dura, pericardia, heart  
3 valves, veins, neural tissue, submucosal tissue, dermis, or cartilage, or combinations  
4 thereof.

1 8. The process according to claim 5, wherein said sterilization is achieved through a  
2 process that retains the bioactive properties of said at least one tissue sample.

1 9. The process according to claim 8, wherein said sterilization is achieved using a  
2 process selected from the group consisting of BioCleanse, acid wash, boiling, 100%  
3 ethanol, gamma radiation, ethylene oxide, disinfectants, broad spectrum antibiotic  
4 solutions or combinations thereof.

1 10. The process according to claim 5, wherein said scanning comprises disposing said at  
2 least one tissue sample in a container that interfaces with at least one scanning device  
3 positioned in, on, or proximate to said container to effectuate scanning of said tissue  
4 sample.

1 11. The process of claim 10, wherein said scanning device is enabled to scan said at least  
2 one tissue sample in x, y, or z coordinate planes, or combinations thereof.

1 12. The process of claim 11, wherein said scanning device generates dimensional data  
2 corresponding to the size and shape of said scanned tissue sample.

- 1 13. The process according to claim 5, wherein said computer system is enabled with a  
2 graphical software program designed to produce images.
- 1 14. The process according to claim 13, wherein said dimensional data is converted into  
2 numerical data.
- 1 15. The process of claim 14, wherein said numerical data is converted into an image by  
2 said graphical software program.
- 1 16. The process of claim 5, wherein said identifying step utilizes an algorithm to match  
2 said data with one or more preferred designs from said database relating to an optimal  
3 use of said tissue sample.
- 1 17. The process of claim 16, wherein said data is matched with said one or more  
2 preferred designs based on similarity of dimensions.
- 1 18. The process of claim 5, wherein said database is generated from compiling  
2 dimensional data from previously manufactured tissue implants.
- 1 19. The process of claim 5, wherein upon identifying said one or more template designs  
2 and number thereof, said at least one tissue sample is directed to a specific  
3 machining device selected from a plurality of machining devices, wherein said  
4 specific machining device is configured to machine said sorted tissue in accord with  
5 said template design.
- 1 20. The process of claim 5, further comprising cutting said at least one tissue sample into  
2 a blank prior to said machining, whereby said blank is cut to have dimensions  
3 appropriate for subsequent machining into said one or more designs and quantity  
4 thereof.

- 1 21. The process of claim 20, wherein said machining is conducted by a milling device  
2 that is contained in its own environment to thereby prevent contamination from the  
3 environment external to said milling device.
- 1 22. The process of claim 5, wherein said process further comprises inspecting said one or  
2 more tissue products for quality verification.
- 1 23. The process of claim 22, wherein said inspecting is conducted by optical inspection  
2 wherein cameras are positioned for remote viewing of said one or more tissue  
3 products
- 1 24. The process of claim 23, wherein said optical inspection comprises utilizing a  
2 plurality of video cameras, mounted such that separate x, y and z coordinate planes  
3 along said product may be viewed optically to ensure complete inspection of the  
4 product quality to accept or reject said product.
- 1 25. The process of claim 5 comprising packaging said one or more tissue products.
- 1 26. The process of claim 25, further comprising sterilizing said one or more tissue  
2 products by irradiation.
- 1 27. The process of claim 5, wherein sterilizing of at least one tissue sample comprises  
2 disposing said at least one tissue sample in a chamber and sterilizing said tissue in  
3 said chamber; and scanning said at least one tissue sample comprises scanning in  
4 said chamber, such that said at least one tissue sample remains sterilized during said  
5 scanning step.
- 1 28. The process of claim 5, wherein said at least one tissue sample is transferred between  
2 steps in sterilized containers.

1 29. The process of claim 5, wherein subsequent to machining said at least one tissue  
2 sample, said tissue is packaged, sterilized and stored.

1 30. The process according to claim 29, wherein package sterilization is achieved through  
2 Sterrad sterilization procedures.

1 31. An automated tissue processing system comprising:  
2 a sterilization chamber; an optimizer unit comprising at least one scanning device  
3 interfaced with at least one computer system enabled by at least one analytical  
4 software program and a database comprising a plurality of template designs; a cutting  
5 device for cutting tissue into a desired tissue blank; a routing device for routing said  
6 tissue to an appropriate milling machine for machining said blank into a desired  
7 product; an inspection station for inspecting the quality of said product; a holding  
8 chamber for holding rejected products; a packaging station for packaging and labeling  
9 accepted products; and a storage station for storing products prior to shipment.

1 32. An automated process for manufacturing implantable tissue products  
2 comprising:

- 3 (a) selecting a tissue sample for processing; placing said tissue sample into a  
4 sterilized chamber, wherein said tissue sample is sterilized;  
5 (b) transferring said sterilized tissue sample into a sterilized optimizer unit,  
6 wherein said tissue sample is scanned to obtain dimensional data  
7 corresponding to said tissue sample;  
8 (c) inputting dimensional data from said sample into a computer system enabled  
9 with an analytical software program and a database comprising a plurality of  
10 designs;  
11 (d) analyzing said dimensional data with said analytical software program to  
12 identify a design type and quantity thereof commensurate with the dimensions  
13 of said tissue sample to maximize tissue utilization;

- 14 (f) routing said tissue sample into a sterilized cutting machine wherein said tissue  
15 sample is cut into a tissue blank of sufficient size and shape to facilitate  
16 subsequent machining of said tissue product according to said design;  
17 (g) transporting said container to a sorter;  
18 (h) placing said blank into said sorter, wherein said blank is routed to a milling  
19 device enabled to machine a design from the blank in accord with said  
20 identified design and quantity thereof;  
21 (i) milling said blank to produce a finished product in accord with said identified  
22 template design and number thereof;  
23 (j) analyzing said finished product for quality;  
24 (k) packaging and labeling said finished product;  
25 (l) sterilizing said packaged product prior to storage; and  
26 (m) storing said sterilized product for at least twenty-four hours.

1 32. An implant produced by the process of claim 1.

1 33. An implant produced by the process of claim 5.

1 34. A process for manufacturing tissue implants comprising:

- 2 a. scanning at least one tissue sample to produce dimensional data corresponding  
3 thereto;  
4 b. inputting said data into a computer system enabled with a database comprising  
5 a plurality of designs;  
6 c. identifying one or more designs and quantity thereof that correspond to an  
7 optimal use of said at least one tissue sample; and  
8 d. routing said at least one tissue sample to a machining device, wherein said  
9 machining device is programmed with the specifications of said identified  
10 design to automatically machine said at least one tissue sample to produce a  
11 tissue product in accord with said identified design.